US009101425B2

(12) **United States Patent**
Douget et al.

(10) **Patent No.: US 9,101,425 B2**
(45) **Date of Patent: Aug. 11, 2015**

(54) **DEVICE AND METHOD FOR SECURING A LIGATURE TO AN OSSEOUS STRUCTURE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 512 days.

(21) Appl. No.: **13/309,995**

(22) Filed: **Dec. 2, 2011**

(65) **Prior Publication Data**

US 2012/0303121 A1 Nov. 29, 2012

(30) **Foreign Application Priority Data**

Dec. 16, 2010 (EP) 10306428

(51) **Int. Cl.**
A61B 17/70 (2006.01)
A61B 17/82 (2006.01)
A61B 17/84 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 17/82*** (2013.01); ***A61B 17/7053*** (2013.01); ***A61B 17/84*** (2013.01); ***A61B 17/842*** (2013.01); *A61B 17/707* (2013.01)

(58) **Field of Classification Search**
CPC A61B 17/7022; A61B 17/7053; A61B 17/82; A61B 17/823; A61B 17/842; A61B 17/84
USPC ..... 606/74, 103, 228, 232, 263, 277, 279, 606/283, 300, 324, 328; 24/122.6, 136 R, 24/136 L, 115 G, 115 M
See application file for complete search history.

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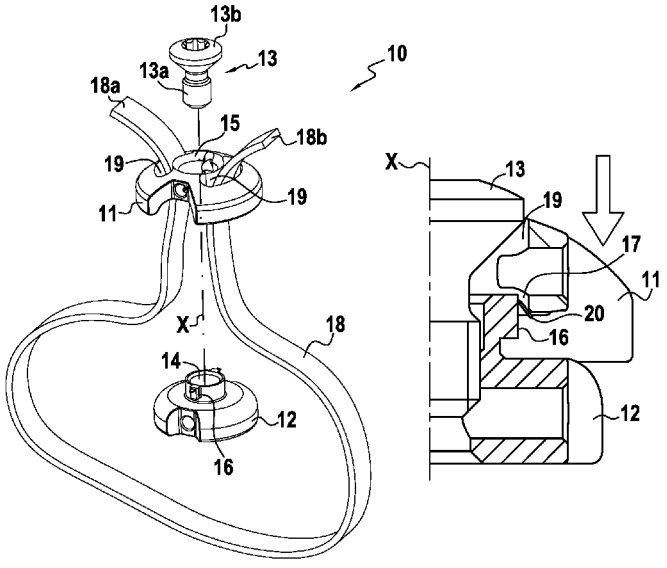
(57) **ABSTRACT**

Embodiments disclosed herein provide a device for securing a ligature to an osseous structure, the device comprising a first part, a second part, a flexible elongate member for engaging the osseous structure, a closure element, and a deformable element between the first and second parts for holding open a gap G between them. The flexible elongate member is threaded through an orifice in the first part and the gap G. The closure element is configured for clamping the first and second parts against each other, overcoming the resilience of the deformable element, so as to frictionally lock the flexible elongate member threaded through the gap G. Embodiments disclosed herein also provide a method for using the device.

11 Claims, 5 Drawing Sheets



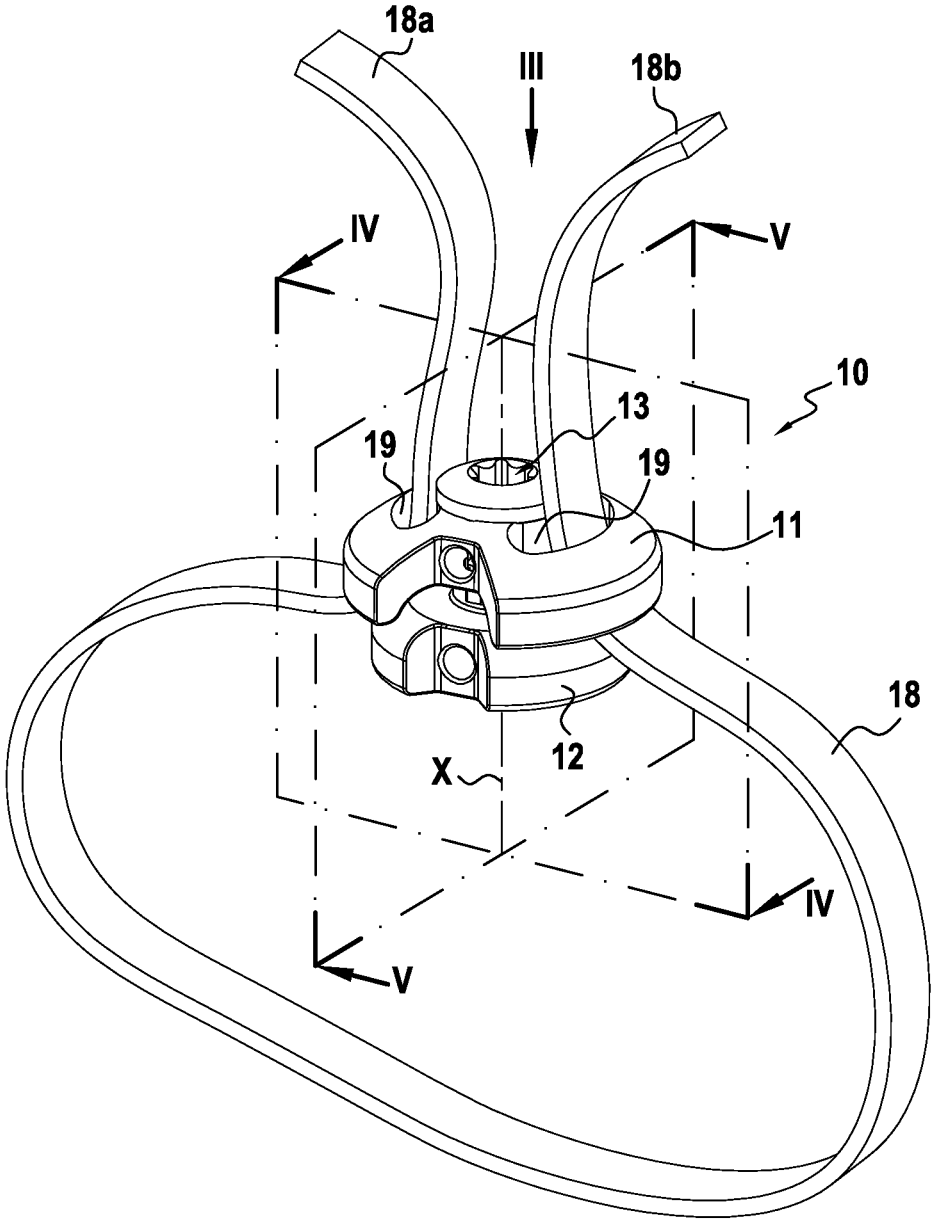


FIG.1

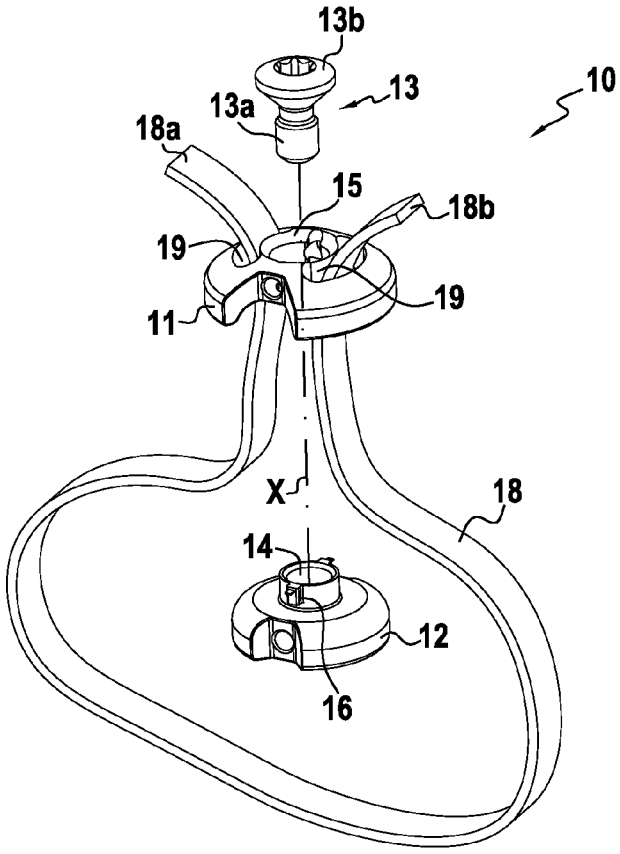

13b
13
10
13a
18a
15
18b
19
19
11
X
18
14
12
16

FIG.2

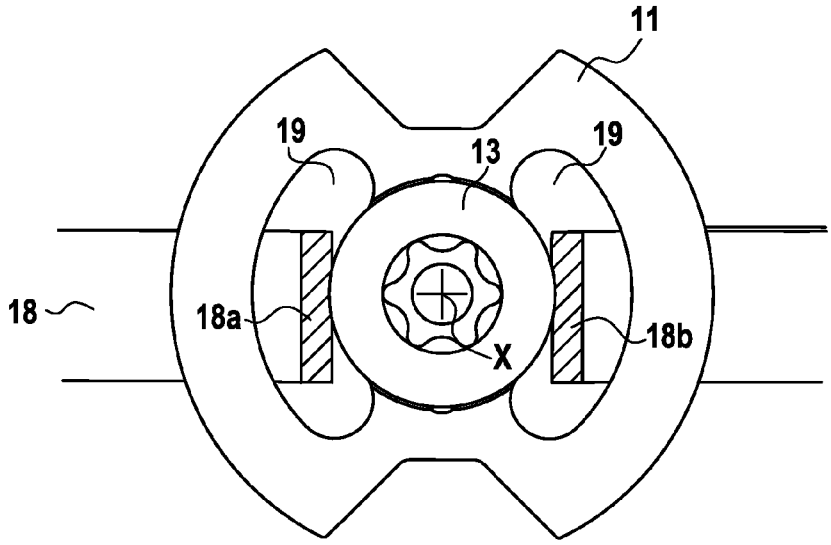

11
19
13
19
18
18a
18b
X

FIG.3

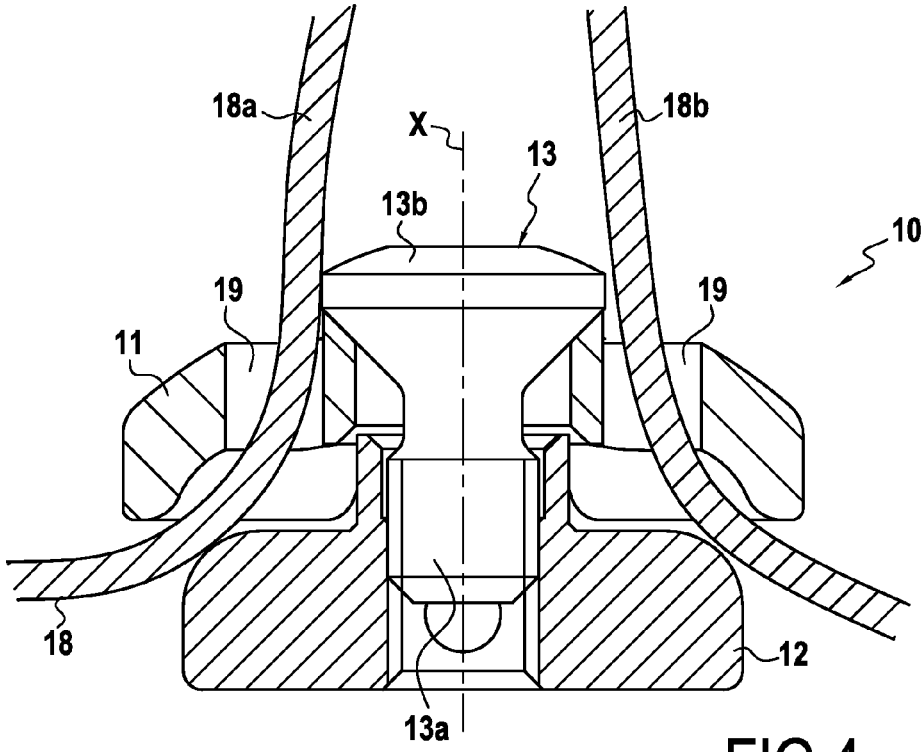

18a
X
18b
13
13b
10
19
19
11
18
12
13a

FIG.4

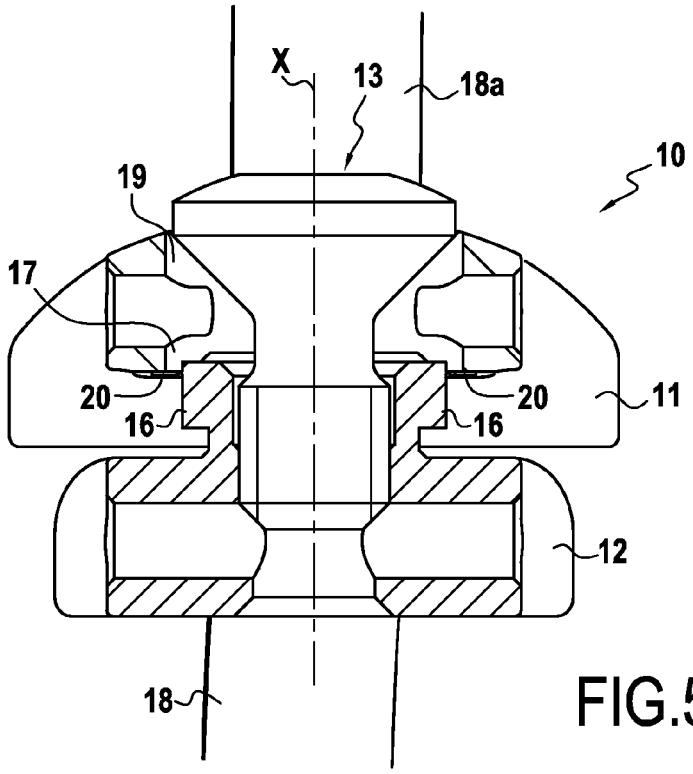

X
13
18a
10
19
17
20
20
11
16
16
12
18

FIG.5

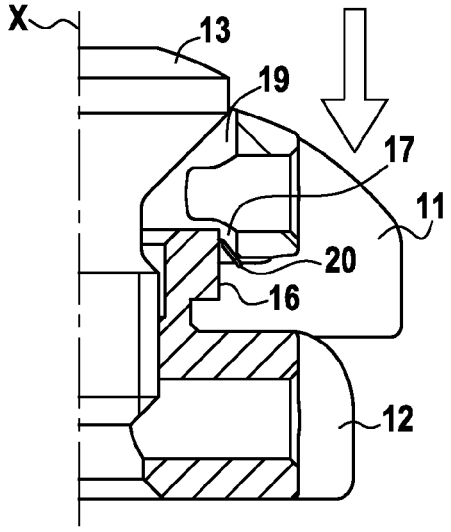


FIG.6A

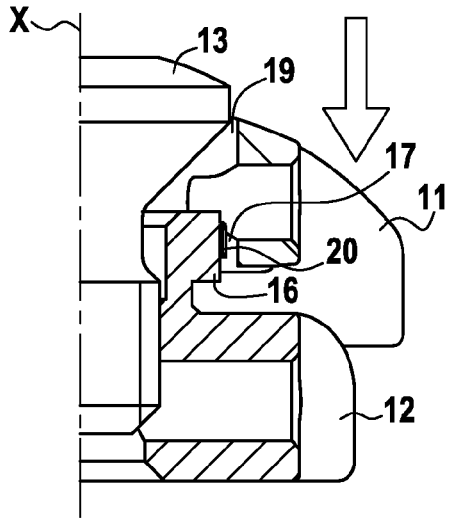


FIG.6B

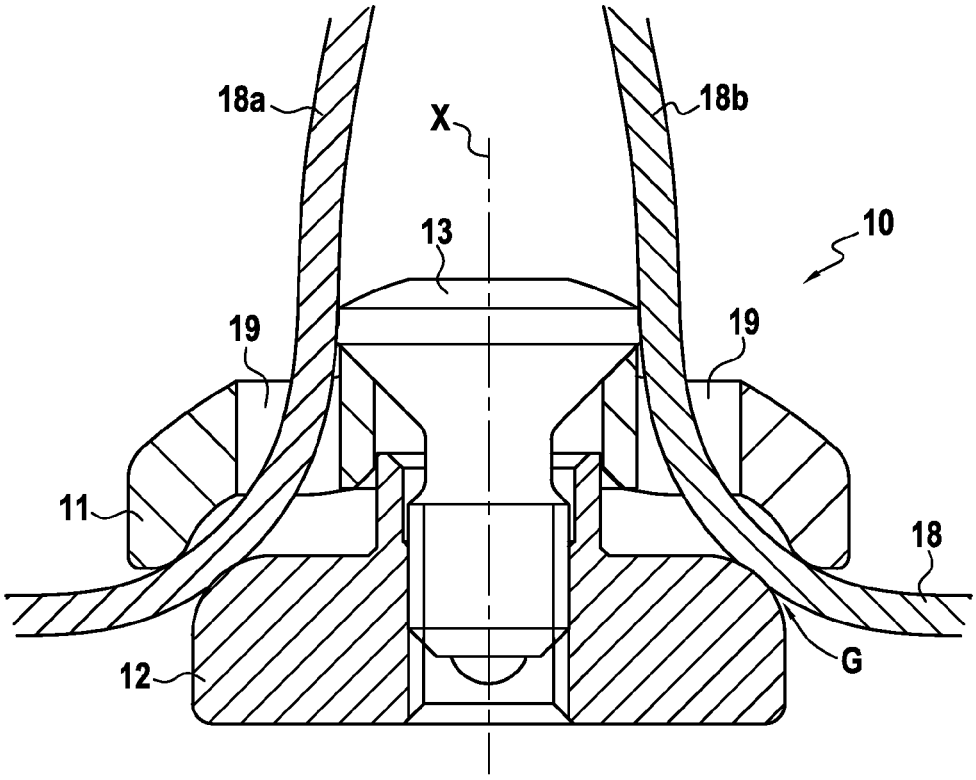


FIG.7

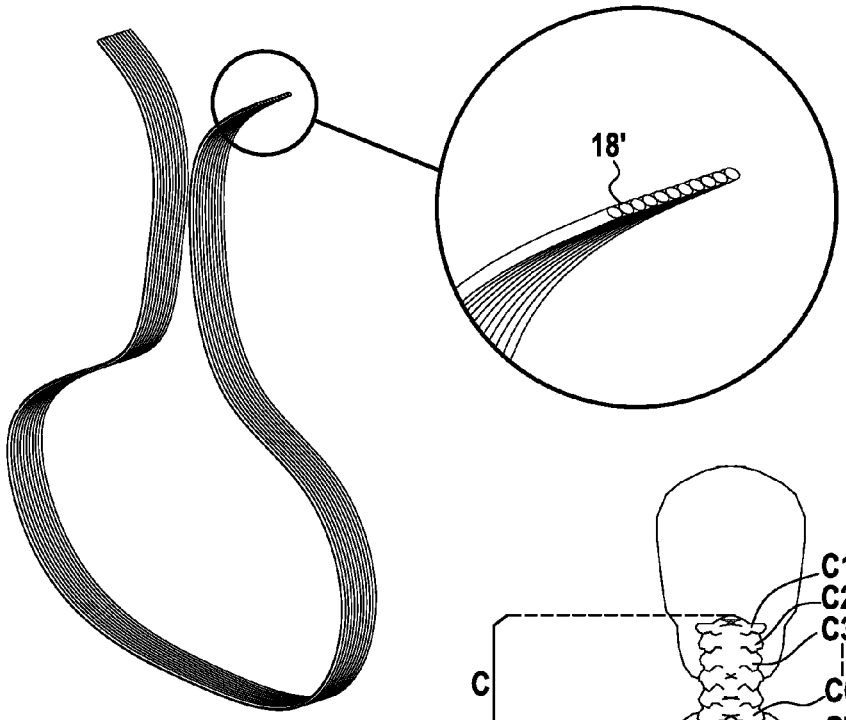


FIG.8

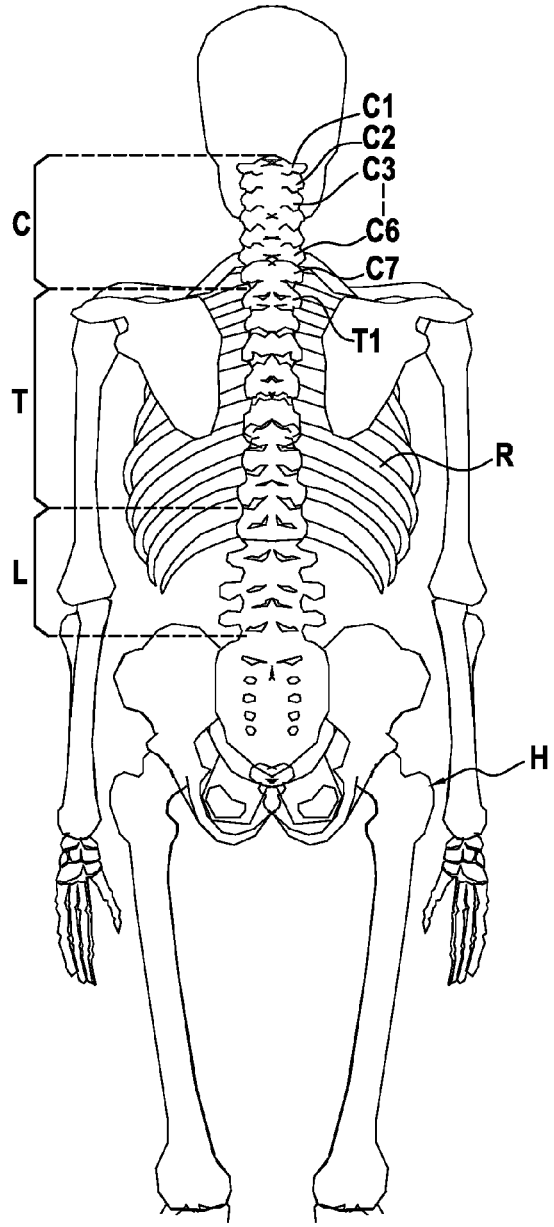


FIG.9

DEVICE AND METHOD FOR SECURING A LIGATURE TO AN OSSEOUS STRUCTURE

TECHNICAL FIELD

Embodiments relate to a device and a method for securing a ligature to an osseous structure, in particular for reinforcing, or stabilizing the osseous structure, or for correcting a deformity in the osseous structure.

BACKGROUND

In all vertebrate animals, including humans, osseous structures provide an essential solid framework for the body. Injury, age or disease may however damage these osseous structures. In order to repair or at least alleviate such damage, various medical and surgical techniques have been proposed. In particular, a number of surgical techniques have been proposed using wire ligatures to reinforce or correct such injured, diseased, or otherwise damaged osseous structures.

Surgical wiring techniques have in particular been applied for treatment of the spine, and more especially of upper cervical fractures and thoraco-lumbar fractures. For example, the Gallie and Brooks atlanto-axial stabilization techniques using wires can be used for the treatment of Type II and III C2 odontoid fractures, i.e., fractures at the base of the C2 odontoid or transversally to the body of the C2 vertebra; as well as Type III C2 traumatic spondylolisthesis, i.e., C2 "hangman fractures" with severe displacement and angulation. The Wertheim and Bohlman occipitocervical stabilization technique can be used for the treatment of fractures of the closed ring of the C1 vertebra, as well as for the stabilization of the C1-C2 segment when affected by rheumatoid arthritis.

Trauma, such as distractive flexion injuries with facet disruption and dislocation, or ligamentous injuries, to other cervical segments, for instance at the C5-C6 level or at the fulcrum between cervical and thoracic spine, can be treated using subaxial cervical stabilization with such wiring techniques as the Rogers technique, the Bohlman triple wire technique, the Dewar technique, or the Robinson and Southwick facet wiring technique.

Finally, among the thoraco-lumbar fractures that can be reduced and stabilised using wiring techniques, and in particular Harrington rods with sublaminar wires and interspinous wires, are compression fractures, flexion distraction fractures ("seatbelt fractures"), and dislocated fractures.

However, the metallic wires used in such wiring techniques present some drawbacks, in particular with respect to biocompatibility, strength, stability and material fatigue, and stress concentrations where they contact the bones. Even more significantly, adjusting the wire tension while tying the wire requires very high dexterity, and may be even more difficult once the wire is tied.

In the prior art, it has also been proposed to use flexible elongated elements other than wires to tie various implants to underlying osseous structures. In particular, intervertebral implants have been proposed which are tied to the vertebrae using flat bands, for instance in International Patent Application publication WO 2009/040380. Such flat bands have the advantages of higher biocompatibility, strength and stability, as well as better stress distribution on the bones. While adjusting the band tension remains difficult, this is less critical in this application, since the main stresses go through the body of the intervertebral implant, rather than the flat band.

SUMMARY

A first object of the disclosure is that of providing a device for securing a ligature to an osseous structure, wherein the tension in the ligature can be more easily adjusted than with previous devices and methods.

Accordingly, a device for securing a ligature to an osseous structure according to at least one illustrative embodiment of the disclosure comprises a first part, a second part, a flexible elongate member for engaging the osseous structure, the flexible elongated member being threaded through an orifice in the first part and a gap between the first and second parts, a closure element for clamping the first and second parts against each other so as to frictionally lock the flexible elongate member threaded through the gap between the first and second parts, and a deformable element between the first and the second part, which in an initial, undeformed position is suited to hold open said gap, and which in a second, deformed position allows the gap to be narrowed.

Because the deformable element holds the gap open in its undeformed position, the flexible elongate element remains free to slide through the gap, and the tension of the flexible elongate element can be easily adjusted without having to simultaneously hold the first and second parts apart from each other. The first and second parts can nevertheless be subsequently clamped against each other using the closure element, deforming the deformable element so that the gap is narrowed, and frictionally locking the flexible elongate member within this gap between the first and second parts.

The deformable element may be plastically or elastically deformable between said undeformed and deformed positions, wherein an elastically deformable element can provide an advantage of recovering its function of holding open the gap between the first and second parts if the closure element is subsequently released. On the other hand, a plastically deformable element may be more easily provided, and at a lower cost.

In some embodiments, the deformable element is solid with the first and/or the second part, reducing the number of separate parts of the device, thus simplifying both its production and operation and reducing the risk of incorrect assembly.

In some embodiments, the closure element is screw-threaded. In particular, said closure element may comprise a shank with an outer screw thread in engagement with a complementary inner screw thread in one of the first or second parts, and a head in engagement with the other one of the first or second parts. Consequently, the first part and the second part can easily be clamped against each other by tightening the closure element.

In some embodiments, the flexible elongate member has a first end and a second end, and each one of the first end and the second end is threaded through an orifice in the first part and a gap between the first and second parts. Consequently, both ends of the flexible elongate member can be simultaneously locked by closing the first part and the second part against each other.

Among some of these embodiments, each one of the first and second ends of the flexible elongate element is separately threaded through the gap. In particular, the first end of the flexible elongate element may be threaded through a first orifice in the first part, and the second end of the flexible elongated element may be threaded through a second orifice in the first part. The first and second ends of the flexible elongate element can thus be laterally offset with respect to each other, providing a more versatile ligature.

In some embodiments, the closure element is configured to releasably clamp the first and second parts against each other. The first and second parts could thus be released from each other after being clamped against each other, thus allowing a readjustment of the tension in the flexible elongate member.

In some embodiments, the flexible elongate member may comprise a flat band or a plurality of strands, in particular arranged side-by-side. Consequently, the stresses transmitted by the band or strands to the osseous structure are distributed over a wide area, preventing further damage to the bone structure.

Another object of the disclosure is that of providing an easier, safer method of securing a ligature to an osseous structure.

Accordingly, in at least an illustrative embodiment of the disclosure, a method for securing a ligature to an osseous structure comprises the steps of looping a flexible elongate member around at least part of the osseous structure, threading the flexible elongate member through a gap between the first part and the second part and an orifice of the first part, tensioning the flexible elongate member, so that the first and second parts are tightly bound to the osseous structure, and tightening a closure element between the first and second parts, so as to tighten the gap between the first and second parts against a resilience of a deformable element, and frictionally locking the flexible elongate element in the tightened gap between the first and second parts.

Because the resilience of the deformable element has to be overcome to tighten the gap and lock the flexible elongate member, the tension in said flexible elongate member remains easily adjustable until the closure element is actively operated, against the resilience of said deformable element, to clamp the first and second parts against each other.

In some embodiments, the flexible elongate member is threaded twice through the gap between the first part and the second part, so that both ends of the flexible elongate member can be frictionally locked by the tightening gap when the closure element is operated to close the first and second parts against each other.

In some embodiments, the osseous structure comprises a spine segment. In particular, it may comprise a cervical segment. The method according to the disclosure may be used, for instance, to treat Type II and III C2 odontoid fractures or Type III C2 traumatic spondylolisthesis with an upper cervical ligature according to the Gallie and Brooks atlanto-axial stabilization techniques. It may also be used for the treatment of fractures of the closed ring of the C1 vertebra, as well as for the stabilization of the C1-C2 segment when affected by rheumatoid arthritis, with an upper cervical ligature according to the Wertheim and Bohlman occipitocervical stabilization technique. Trauma to other cervical segments, such as distractive flexion injuries with facet disruption and dislocation, or ligamentous injuries, for instance at the C5-C6 level or at the fulcrum between cervical and thoracic spine, may be treated with a ligature to a corresponding spine segment following a known subaxial cervical stabilization technique. It must be understood that, although those techniques conventionally apply wires, according to the method a flat band or a plurality of strands may be tied to the osseous structure analogously to those wires, which has the additional advantage of distributing the contact stresses over wider areas of the bones.

The osseous structure may however also comprise a thoracic or lumbar segment. The method according to the disclosure may for instance be used to stabilise a thoraco-lumbar segment in case of a compression fracture, flexion distraction fracture, or dislocated fracture.

The method according to the disclosure may even be used to secure a ligature to other osseous structures than the spine, such as e.g. long bones, to secure implants and/or treat fractures. For instance, this method may be used for providing a rod-less arthrodesis, or for stabilizing a hip bone by trochanteric fixation using, for example, the Dall-Miles technique, or in hip revision surgery to prevent vessel necrosia or for a complementary rib ligature exerting a lateral rib traction for scoliosis correction.

The above summary of some example embodiments is not intended to describe each disclosed embodiment or every implementation of the invention. In particular, selected features of any illustrative embodiment within this specification may be incorporated into an additional embodiment unless clearly stated to the contrary.

BRIEF DESCRIPTION OF THE DRAWINGS

The disclosure may be more completely understood in consideration of the following detailed description of various embodiments in connection with the accompanying drawings, in which:

FIG. **1** is a perspective view of a device according to a first embodiment;

FIG. **2** is an exploded perspective view of the same device;

FIG. **3** is a top view of the device of FIG. **1**;

FIG. **4** is a cut view of the device of FIG. **1** through plane IV-IV;

FIG. **5** is a cut view of the device of FIG. **1** through plane V-V;

FIGS. **6**A and **6**B show detail cut views of the device of FIG. **1** through the same plane V-V, at successive stages of its operation to secure a ligature;

FIG. **7** shows a detail cut view of the device of FIG. **1** through plane IV-IV when the ligature is secured;

FIG. **8** shows a section of a flexible elongate element of a device according to a second embodiment; and

FIG. **9** shows a number of potential positions in a human skeleton for a ligature secured with the device of FIG. **1**.

While the embodiments are amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit aspects of the invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the scope of the claims.

DETAILED DESCRIPTION

For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

As used in this specification and the appended claims, the singular forms "a", "an", and "the" include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise.

The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The detailed description and the drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention. The illustrative embodiments depicted are intended only as exemplary. Selected features of any illustrative embodiment may be incorporated into an additional embodiment unless clearly stated to the contrary.

A device **10** for securing a ligature to an osseous structure according to a first embodiment is shown in FIGS. **1** and **2**. In this particular embodiment, the device **10** is disc-shaped, which is an advantageous shape for its ease of handling and unobtrusiveness once implanted, but other alternative shapes

may also be considered. This device **10** comprises a first part **11** and a second part **12** linked by a closure element **13** in the form of a screw with a screw-threaded shank **13***a* in engagement with a complementarily screw-threaded orifice **14** in the second part **12**, and a head **13***b* in engagement with a recess **15** in the first part **11**. Guiding blocks **16** protruding laterally from the second part **12** engage corresponding recesses **17** in the first part **11** to suppress rotation between the first and the second parts **11**,**12**, while still allowing their translation, relative to each other, along the longitudinal axis X of the screw **13**.

The device **10** also comprises a flat, flexible band **18** adapted to form a ligature to an osseous structure. This band **18** is made of a biocompatible material, in particular comprising synthetic materials such as, but not limited to, polyester, polyethylene terephtalate (PET), ultra-high-molecular-weight polyethylene (UHMPE), or polyetheretherketone (PEEK).

While this first embodiment of the device **1** comprises a flat band **18**, other types of flexible elongate members may alternatively be used for the ligature. For instance, in a second embodiment, a plurality of separate, substantially parallel strands **18'**, as illustrated in FIG. **8**, could be used in place of the flat band of the first embodiment. The other parts of the device for securing this ligature to an osseous structure could be substantially equivalent to those of the first embodiment, and the device could be used analogously.

Turning back to the first embodiment, each end **18***a*, **18***b* of the band **18** is threaded through one orifice **19** in the first part **11**, and a gap G between the first part **11** and the second part **12**, as can be seen in particular in FIGS. **3** and **4**. As illustrated in FIG. **5**, deformable, wing-shaped elements **20** protruding from each block **16** initially maintain this gap G, holding the bodies of the first and second part **11**, **12** apart from each other.

In use, the width of the gap G initially maintained by the deformable elements **20** allows the band **18** to slid through the gap G and the orifices **19**. Consequently, a user can easily make a ligature to an osseous structure using the band **18**, and adjust the tension of the band **18** before securing this ligature. To secure the ligature the screw **13** is tightened in the orifice **14**. Longitudinally guided by the blocks **16** in the recesses **17**, the first and second parts **11**, **12** will approach each other, progressively overcoming the resilience of the deformable elements **20** and bending them, as seen in FIG. **6**A and FIG. **6**B, until arriving to a deformed position in which the gap G is so tightened that the first and second parts **11**, **12** clamp around the band **18**, as seen in FIG. **7**, frictionally locking the band **18**, and thus securing the ligature.

The screw **13** may be subsequently loosened again to readjust the band **18**. If the deformable elements **20** have only been elastically deformed, they will return to their initial position illustrated in FIG. **5**, holding the gap G open again. However, they will normally have been plastically deformed and will not return to their initial position. For a simple readjustment of the band **18**, this will nevertheless not constitute a significant drawback for the user.

FIG. **9** illustrates several possible locations, in a human skeleton, for a ligature secured with the device **1**. For instance, the ligature may be located in the upper cervical segment C1-C2 for the treatment of Type II and III C2 odontoid fractures, Type III C2 traumatic spondylolisthesis, fractures of the closed ring of the C1 vertebra, or for the stabilization of the C1-C2 segment when affected by rheumatoid arthritis. Such a ligature may also be used in the treatment of trauma to other cervical segments, such as distractive flexion injuries with facet disruption and dislocation, or ligamentous injuries, for instance at the C5-C6 level or at the fulcrum C7-T1 between cervical spine C and thoracic spine T, or to stabilise a segment of the thoracic spine T or lumbar spine L in case of a compression fracture, flexion distraction fracture, or dislocated fracture. The ligature may also might be applied also on other bony structures, such as e.g. long bones, to secure implants and/or treat fractures. It may, for instance, be used to stabilise a hipbone H, to exert a traction between ribs R, or to block any suitable joint by arthrodesis without rods.

Those skilled in the art will recognize that the invention may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. Accordingly, departure in form and detail may be made without departing from the scope of the invention as described in the appended claims.

The invention claimed is:

1. A device for securing to an osseous structure, comprising:

a first part;

a second part;

a ligature including a flexible elongate member for engaging the osseous structure, the flexible elongate member being threaded through an orifice in the first part and a gap between the first and second parts;

a closure element extending through the first part and engaging with the second part for clamping the first and second parts against each other so as to frictionally lock the flexible elongate member threaded through the gap between the first and second parts; and

a deformable element between the first part and the second part, which in an initial, undeformed position is suited to hold open said gap, and which in a second, deformed position allows the gap to be narrowed;

wherein the deformable element is plastically deformable between said undeformed and deformed positions;

wherein said closure element is screw-threaded.

2. The device for securing to an osseous structure according to claim **1**, wherein the deformable element is solid with the first and/or the second part.

3. The device for securing to an osseous structure according to claim **1**, wherein said closure element comprises a shank with an outer screw thread in engagement with a complementary inner screw thread in one of the first or second parts, and a head in engagement with the other one of the first or second parts.

4. The device for securing to an osseous structure according to claim **1**, wherein the flexible elongate member has a first end and a second end, and each one of the first end and the second end is threaded through the orifice in the first part or a second orifice in the first part, and through the gap between the first and second parts.

5. The device for securing to an osseous structure according to claim **4**, wherein each one of the first and second ends of the flexible elongate member is separately threaded through the gap.

6. The device for securing to an osseous structure according to claim **5**, wherein the first end of the flexible elongate member is threaded through the orifice in the first part, and the second end of the flexible elongate member is threaded through the second orifice in the first part.

7. The device for securing to an osseous structure according to claim **1**, wherein the closure element is configured to releasably clamp the first and second parts against each other.

8. The device for securing to an osseous structure according to claim **1**, wherein the flexible elongate member comprises a flat band.

9. The device for securing to an osseous structure according to claim 1, wherein the flexible elongate member comprises a plurality of strands.

10. A device for securing to an osseous structure, comprising:

a first part;

a second part;

a ligature including a flexible elongate member for engaging the osseous structure, the flexible elongate member being positioned through an orifice in the first part and between a surface of the first part and a surface of the second part;

a closure element passing through the first part and engaging with the second part for clamping the flexible elongate member between the surface of the first part and the surface of the second part so as to frictionally lock the flexible elongate member with respect to the first and second parts; and

a deformable element interacting with the first part and the second part, which in an initial, unlocked position is configured to hold apart the surface of the first part and the surface of the second part to permit the flexible elongate member to move between the surface of the first part and the surface of the second part, wherein upon actuation of the closure element to clamp the flexible elongate member between the surface of the first part and the surface of the second part, the deformable element is deformed to a second, deformed position in which the surface of the first part and the surface of the second part are closer together;

wherein the deformable element is plastically deformable from the initial, unlocked position to the second, deformed position;

wherein the closure element threadably engages the second part to apply a clamping force to the flexible elongate member.

11. The device for securing to an osseous structure according to claim 10, wherein a first end of the flexible elongate member is threaded through the orifice in the first part, and a second end of the flexible elongate member is threaded through a second orifice in the first part.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO.	: 9,101,425 B2
APPLICATION NO.	: 13/309995
DATED	: August 11, 2015
INVENTOR(S)	: Douget et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the title page, item 30, in "Foreign Application Priority Data", in column 1, line 1, delete "10306428" and insert --10 306 428.3--, therefor

Signed and Sealed this
Ninth Day of February, 2016

Michelle K. Lee

Michelle K. Lee
Director of the United States Patent and Trademark Office